REMARKS/ARGUMENTS

The Claim Rejections

A. Claims 1, 5-7, 11, 15-17, and 19

Claims 1, 5-7, 11, and 15-19 stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Mele (2002).

B. Claims 1, 5, 11, 15, and 19

Claims 1, 5, 11, 15, and 19 stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Mele (1998).

C. Claims 1, 6, and 7

Claims 1, 6, and 7 stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Pfitzner.

D. Claims 5 and 7

Claims 5 and 7 stand rejected under the provisions of 35 U.S.C. § 102(b) as being anticipated by Szente.

E. Claims 1, 5-7, 11, and 15-19

Claims 1, 5-7, 11, and 15-19 stand rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Mel (2002).

F. Claims 1, 5-7, 11, and 15-19

Claims 1, 5-7, 11, and 15-19 stand rejected under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Mele (2002) in view of either Mele (1998) or Szente.

G. Argument

Submitted herewith is an additional declaration from Dr. Madhavi, one of the co-inventors and co-applicants in which she reports additional data. Specifically, Dr. Madhavi repeated the process taught by Mele for the preparation of a lutein-γ-CD complex. Mele does not report a yield figure. Dr. Madhavi's results showed a very poor complexation yield for the Mele process based on product weight. In contradistinction, Applicants report a high yield, making Applicants' process amenable to commercial scale-up. This is not true for the Mele process.

Differential Scanning Calorimetry analysis showed the Mele yield to be ~4%--that is, ~96% of the lutein remained uncomplexed in the Mele process. Applicants process, however, showed a nearly 88% complexation yield by Differential Scanning Calorimetry analysis.

Next, Dr. Madhavi characterized a freeze-dried lutein-γ-CD complex and a spray-dried lutein-γ-CD complex. The results of the study indicate the freeze-dried complex formed a suspension in water fairly easily, as compared to the spray-dried complex. The spray-dried complex also showed a tendency to form aggregates in water. The results of Differential scanning Calorimetry analysis indicated that on spray-drying, there is a change in the degree of complexation and, possibly, a change in the physical properties of the complex—not observed for the freeze-dried material. Again, the uniqueness of Applicants process and product is underscored.

With respect to the Examiner's comments on bioavailability of the lutein/γ-CD complex without excipients, Dr. Madhavi conducted a small crossover human study to demonstrate the uptake of the lutein/γ-CD powder without any excipients and to compare the uptake of spray-dried and freeze-dried lutein/γ-CD complex without any added excipients. The results clearly showed that the freeze-dried complex is more bioavailable than the spray dried complex *in vivo*. Furthermore, the lutein from the complex is bioavailable without any added excipients *in vivo*. Excipients are added to these formulations not for activity, but for achieving industry desired shelf-life. These results confirm such.

With respect to the Examiner's comments on the degradation of lutein before absorption, Dr. Madhavi conducted an experiment designed to demonstrate the stability of lutein complexed with γ-CD on exposure to simulated gastric fluid. The results demonstrate that both the spray-dried and the freeze-dried complexes remained stable at pH 1.2 for the duration the ingested food or supplement is exposed to acidic pH in the stomach. Again, the Examiner's suppositions without citation to authority are disproved.

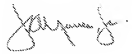
The Examiner is invited to review the experimental conditions and results in greater detail in the attached declaration of Dr. Madhavi.

These results confirm Applicants' analysis of the art and conclusion that the cited art does not anticipate nor render obvious the claims.

H. Summary

In view of submitted declaration and the remarks herewith, allowance of all claims and passage to issue of this application respectfully is requested.

Respectfully submitted,



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